

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

VALEANT PHARMACEUTICALS
NORTH AMERICA LLC,

Plaintiff,

v.

BELCHER PHARMACEUTICALS, LLC,
et al.,

Defendants.

Case No. [17-cv-06731-RS](#)

**ORDER DENYING MOTIONS TO
DISMISS**

I. INTRODUCTION

This case was originally brought against multiple unrelated defendants. Pursuant to a stipulation of the parties, the claims against various defendants, or defendant groups, were severed into separate actions. The defendants remaining in this matter are Virtus Pharmaceuticals, LLC, (“Virtus LLC”) and Virtus Pharmaceuticals OPCO II, LLC (“OPCO”) (collectively “the Virtus entities”).¹

In two separate motions, the Virtus entities seek dismissal (1) for lack of personal jurisdiction, (2) for improper venue, (3) on the basis of the “primary jurisdiction” doctrine, and/or, (4) for assorted other alleged pleading defects. Although OPCO has made an adequate showing that it is not subject to personal jurisdiction in this forum and must be dismissed, the motions will

¹ An additional defendant not severed from this case, Belcher Pharmaceuticals, LLC, has since been dismissed by stipulation.

be denied as to Virtus, LLC.

II. BACKGROUND

Plaintiff, Valeant Pharmaceuticals North America, LLC manufactures, markets, and sells Librax® (hereinafter, “Librax”), a drug approved by the FDA for treatment of gastritis, peptic ulcers, and irritable bowel syndrome. Librax consists of 2.5 mg clidinium bromide and 5 mg chlordiazepoxide hydrochloride. Librax allegedly has been reviewed, determined to be safe and effective for the indicated use, and on that basis approved for marketing in the United States by the FDA.

The Virtus entities allegedly manufacture, market, and/or sell various versions of a drug (the “accused products”) that also purportedly consists of 2.5 mg clidinium bromide and 5 mg chlordiazepoxide hydrochloride. Valeant asserts, however, that the accused products (1) have not been evaluated for safety and effectiveness by the FDA or the state of California, and (2) have not been approved under the Federal Food, Drug and Cosmetic Act (“FDCA”) or any relevant California act or agency. Valeant contends the Virtus entities’ marketing of the accused products is deceptive and actionable because they promote them as “‘generic’ versions – *i.e.*, FDA-approved copies – of Librax.” Valeant sets out claims for relief under the Lanham Act, California’s UCL (Cal. Bus. & Prof. Code § 17200) and California’s False Advertising Law (Cal. Bus. & Prof. Code § 17500).

III. DISCUSSION

A. Personal jurisdiction

When there is no applicable federal statute governing personal jurisdiction, the law of the state in which the district court is located applies. California’s long-arm statute, Cal. Code Civil Procedure § 410.10, permits the exercise of jurisdiction “on any basis not inconsistent with the Constitution of this state or of the United States.” *Rocke v. Canadian Automobile Sport Club*, 660 F.2d 395, 398 (9th Cir. 1981). Accordingly, the exercise of jurisdiction must comport with due process. A defendant who is not present in the forum may be subject to jurisdiction only when he

has certain minimum contacts with the forum state such that maintenance of the suit does not offend traditional notions of fair play and substantial justice. *International Shoe Co. v. Washington*, 326 U.S. 310, 316, 66 S.Ct. 154 (1945).

In judging minimum contacts, a court properly focuses on “the relationship among the defendant, the forum, and the litigation.” *Shaffer v. Heitner*, 433 U.S. 186, 204, 97 S.Ct. 2569 (1977). The Supreme Court has held that a non-resident’s allegedly intentional and tortious acts expressly aimed at a California resident are sufficient to trigger jurisdiction over that non-resident. *Calder v. Jones*, 465 U.S. 783, 789-90, 104 S.Ct. 1482 (1984).

The party seeking to invoke the jurisdiction of the federal court shoulders the burden of establishing that such jurisdiction exists. *Data Disc, Inc. v. Systems Technology Assoc.*, 557 F.2d 1280, 1285 (9th Cir.1977). Personal jurisdiction may arise from general jurisdiction or specific jurisdiction. To establish general jurisdiction, the defendant’s activities within the forum state need to be “continuous and systematic” or “substantial” such that the state is considered to have a sufficient relationship with the defendant. *Lake v. Lake*, 817 F.2d 1416, 1420 (9th Cir.1987). The standard for establishing general jurisdiction is high, and requires that the defendant’s contacts with the forum state “approximate physical presence.” *Tuazon v. R.J. Reynolds Tobacco Co.*, 433 F.3d 1163, 1169 (9th Cir.2006) (citing *Bancroft & Masters, Inc. v. Augusta Nat’l Inc.*, 223 F.3d 1082, 1086 (9th Cir.2000)).

Specific jurisdiction may be invoked if there is a relationship between the quality of the defendant’s forum contacts and the particular claims for relief advanced by plaintiff. *Hirsch v. Blue Cross, Blue Shield of Kansas City*, 800 F.2d 1474, 1477 (9th Cir.1986). The Ninth Circuit has set forth a three-part analysis to determine whether specific jurisdiction may attach to a claim arising out of a defendant’s forum-related activities. First, the non-resident defendant must perform some act by which he purposefully avails himself of the privilege of conducting activities in the forum, thereby invoking the benefits and protections of its laws. Second, the claim must be one that arises out of defendant’s forum-related activities. Third, exercise of jurisdiction must be reasonable. *Gray & Co. v. Firstenberg Mach. Co., Inc.*, 913 F.2d 758, 760 (9th Cir.1990). In cases

involving intentional conduct, the “purposeful availing” prong can be satisfied by meeting the “effects test,” which requires: “(1) intentional actions; (2) expressly aimed at the forum state; (3) causing harm, the brunt of which is suffered-and which the defendant knows is likely to be suffered-in the forum state.” See *Calder*, 465 U.S. at 791, 104 S.Ct. at 1488.

Here, there is no real dispute that the only contacts the Virtus entities have with California is that that they sell the accused products in this state as part of their nationwide sales. While the percentage of total sales that involve California customers is not high, it apparently still represents a relatively important market.

Valeant’s suggestion that general jurisdiction might be available based on the Virtus entities continuous sales to California customers is not persuasive, as that does not “approximate physical presence.” See *Tuazon*, 433 F.3d at 1169 (To be subject to general jurisdiction, “a defendant must not only step through the door, it must also sit down and make itself at home.”). The sales, however, are sufficient to support specific jurisdiction because Valeant’s alleged injuries—lost sales due to competitors alleged false advertising—flow directly from those sales.² See, *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 297–98, 100 S. Ct. 559, 567 (1980). (“The forum State does not exceed its powers under the Due Process Clause if it asserts personal jurisdiction over a corporation that delivers its products into the stream of commerce with the expectation that they will be purchased by consumers in the forum State.”)

Additionally, the Supreme Court’s decision last year in *Bristol-Myers Squibb v. Superior Court*, 137 S. Ct 1773, 1781 (2017) is instructive by way of contrast. *Bristol-Myers* was a class action brought in state court alleging a specific drug caused personal injuries to the class members. Specific jurisdiction over *Bristol-Myers* in California was found to exist with respect to claims by those members of the class who purchased the drug here, as their injuries arose directly from those sales. The Court held, however, that no personal jurisdiction existed over *Bristol-Myers* in

² Admittedly, Valeant seeks to recover for its lost sales nationally, so not all of its injuries arise from defendants’ sales in California. For jurisdictional purposes, however, the sales here suffice.

California for any *non-California* plaintiffs, as their injuries were *not* related to the company’s sales in California. Here, of course, Valeant is a non-California plaintiff. The Virtus entities’ attempt to argue that makes it like the non-California plaintiffs in *Bristol-Myers* is misplaced, however, because Valeant’s alleged injuries do arise from defendants’ California sales. Thus, Valeant is in the same position as the California plaintiffs in *Bristol-Myers*, who were entitled to assert personal jurisdiction in this state over the defendant.

That said, Virtus LLC has shown it did not make any sales in California or elsewhere. OPCO is the entity that sells the accused product. Accordingly, dismissal of Virtus LLC for lack a personal jurisdiction is warranted, but the motion must be denied as to OPCO.

B. Venue

The Virtus entities’ contention that this case is improperly venued is premised on the same untenable argument that the California sales of the accused products can be disregarded. Under 28 U.S.C. § 1391(b), a civil action may be brought in a judicial district: (1) in which any defendant resides, if all defendants are residents of the State in which the district is located; (2) *in which a substantial part of the events or omissions giving rise to the claim occurred*, or a substantial part of property that is the subject of the action is situated; or (3) if there is no district in which an action may otherwise be brought as provided in this section, any judicial district in which any defendant is subject to the court’s personal jurisdiction with respect to such action. (Emphasis added). The allegedly wrongful marketing and sales of the accused products in California and plaintiff’s resulting lost California sales render venue proper here.³

C. Primary jurisdiction/FDCA preemption

Librax was found by the FDA to be “safe” in 1961, at a time when the regulations did not

³ The Virtus entities also make an almost passing reference to a transfer for convenience under 28 U.S.C. §1404. They have not met their burden to show such a transfer would be warranted.

1 require the FDA also to approve a drug as “effective.” In the following decades, the assumption
2 was that Librax was still subject to the Drug Efficacy Safety Study Review Program (“DESI”) and
3 therefore not fully “FDA approved.” Under those circumstances, generic versions apparently
4 could be sold without creating a misleading impression that they were also FDA approved.

5 In May of 2016, the FDA issued a notice that Librax actually had received full FDA
6 approval in 1973, pursuant to a settlement of a lawsuit between Valeant’s predecessor and the
7 FDA. As such, Librax is not presently under DESI review. The Virtus entities are challenging the
8 FDA’s change in position, and contend this suit should be dismissed, or perhaps stayed, in
9 deference to administrative proceedings. The Virtus entities are contending, in effect, that there
10 will be no basis to find that the accused products are being marketed unlawfully, if Librax is
11 determined to still be subject to DESI review.

12 Valeant, on the other hand contends these suits are *not* intertwined with anything the FDA
13 may be deciding. According to Valeant, its false advertising claims rest on “two simple facts: (i)
14 Defendants advertise and promote their Accused Product in a manner that represents or implies to
15 purchasers that it is an FDA-approved generic product, or an FDA-approved generic version of
16 Valeant’s FDA-approved Librax product, and (ii) Defendants’ Accused Product is not in fact an
17 FDA-approved generic version of Librax, or any other drug, and as they admit, is not FDA-
18 approved at all.”

19 At this point in time, the FDA considers Librax an approved product. That it may have
20 reached that conclusion in error, or that it might reverse course again does not somehow render the
21 Virtus entities’ alleged current conduct lawful. While it is true that this court cannot decide
22 whether Librax should or should not be deemed approved, adjudicating the claims in these
23 lawsuits does not require that question to be answered, and does not require the court to apply,
24 interpret, or enforce the FDCA. The motion to dismiss under the primary jurisdiction doctrine or
25 FDCA preemption fails.⁴

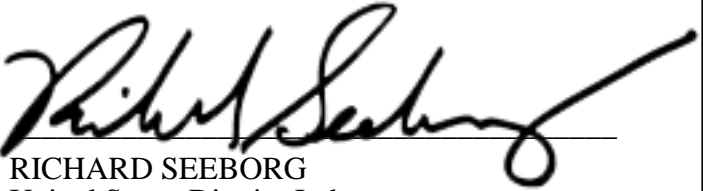
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27 ⁴ The Virtus entities’ remaining arguments effectively seek to strike particular alleged
28 misrepresentations or omissions as inactionable. Such parsing at the motion to dismiss stage is not

1 IV. CONCLUSION

2 The motion to dismiss for lack of personal jurisdiction is granted as to Virtus
3 Pharmaceuticals, LLC. The motions are otherwise denied.

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7 **IT IS SO ORDERED.**

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9 Dated: January 18, 2019

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11 RICHARD SEEBORG
12 United States District Judge

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United States District Court
Northern District of California

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